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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,897	05/19/2006	Breda Mary Cullen	101713-5057	6927

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MORGAN, LEWIS & BOCKIUS LLP
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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1613

MAIL DATE	DELIVERY MODE
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12/06/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,897	Applicant(s) CULLEN ET AL.	
	Examiner BLESSING M. FUBARA	Art Unit 1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 9-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The examiner acknowledges receipt of arguments filed 09/09/2010. No claim is amended. Claims 1-17 remain pending; claims 5 and 9-13 are withdrawn from consideration.

Specification

2. Applicant says that the marked up copy of the specification clearly identifies those portions of the specification amended. However, the examiner thanks the applicant for pointing out that the specification is amended at pages 8 and 9.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-4, 6-8 and 17 remain rejected under 35 U.S.C. 102(b) as being anticipated by Cohen et al. (US 2002/0012693).

5. Cohen describes wound dressing comprising protease inhibitor such as elastase, support matrix such as carboxymethylated cellulose that medically acceptable, and the inhibitors are associated with the support matrix via covalent or ionic linkages (abstract, paragraph [0021] and [0022]). The tetra-peptide and di-or tri-peptide sequences (paragraphs [0023] and [0027]) and these sequences meet claim 8. The covalent or ionic linkages meet the limitation of the linker in claims 1-3 and 4. The carboxymethylated cellulose meets claim 4. Claim 6 recites what

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happens when the level of the enzyme is elevated and as such claim 6 is met. The peptide and the peptide sequences are the substrate for the protease so that claim 7 is met.

Response to Arguments

6. Applicant's arguments filed 09/09/2010 have been fully considered but they are not persuasive.

7. Applicant argues that Cohen does not anticipate the claims because there is no separate wound healing therapeutic agent in the composition Cohen as required by the instant claims.

8. Response: The examiner disagrees because Cohen's wound dressing contains chemical substituents such as amino, carboxylate or pharmaceutically acceptable salts such as alkylamines, procaine and others and also the composition further contains oils; growth factors and skin grafts are also contemplated for use with the wound dressing (see paragraphs [0048]-[0052]. Furthermore, Cohen specifically contemplates using plurality of active agents on the same dressing and other therapeutically beneficial substances such as antibiotics and vitamins (paragraphs [0053]). The wound healing therapeutic agent of the claim reads on antibiotics, vitamins, substituents and oils. The specification does not describe wound healing therapeutic agent or claimed any compounds that may exclude the compounds in Cohen.

9. Claims 1-4, 6, 7 and 14-17 remain rejected under 35 U.S.C. 102(a) as being anticipated by Cullen et al. (GB 2 382 775).

10. Cullen describes wound healing composition comprising polymer matrix that may be cross-linked hyaluronic gels, pain relieving substances or antimicrobial agents, antiseptics, protease inhibitors, proteases selected from elastase (see the whole document with emphasis on the abstract; pages 3 and 4; page 6, line 19 and claims 1-13). The antiseptics and the

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antimicrobials meet the limitation of therapeutic agent and claims 1, 6, 14, 15 are met. The protease inhibitor meets claims 1, the metalloproteinase (page 4, line 19) meet claim 16; claim 17 reads on the wound dressing of Cullen. The cross-linked polymer meets claims 2, 3 and because cross-linked hyaluronic acid is medically acceptable, claims 1-4 are met.

Response to Arguments

11. Applicant's arguments filed 09/09/2010 have been fully considered but they are not persuasive.
12. Applicant argues that Cullen does not teach the claimed matrix and that the barrier taught by Cullen is not required by the instant claims;
13. Response: The examiner disagrees. Cullen teaches cross-linked polymer matrix comprising protease inhibitors, therapeutically active agents such as antiseptics and antimicrobials. The wound healing therapeutic agent of the claim reads on antiseptics and antimicrobials. The comprising language is open and does not exclude the barrier of Cullen as applicant would wish. The target for the proteases in the claims reads on the barrier of Cullen as acknowledged by applicant that the proteases act on the barrier in Cullen.
14. No claim is allowed.
15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618